FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR LICENSING OF PREMISES FOR THE MANUFACTURE OF MEDICAL DEVICES

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APPLICATION FORM FOR LICENSING OF PREMISES FOR THE MANUFACTURE OF MEDICAL DEVICES

APPLICANT'S CHECKLIST		FDA DOUBLE CHECKLIST
☐	Covering Letter	☐
☐	Fully completed Application Form	☐
☐	Signed Declaration	☐
☐	Certificate of Incorporation/Commencement of Business	☐
☐	Site Master File (Where applicable)	☐
☐	Process Flow Diagram (Where applicable)	☐
☐	Administrative Requirement (e.g Environmental Protection Agency (EPA) Permit (*Where applicable*))	☐
☐	Technical Management Agreement with any Organization (*Where applicable*)	☐
☐	Factory Layout/Floor Plan *(Where applicable)*	☐
☐	Personnel Medical Test Certificate *(Where applicable)*	☐

APPLICATION FORM FOR LICENSING OF PREMISES FOR THE MANUFACTURE OF MEDICAL DEVICES

TYPE OF APPLICATION:

☐ New Application ☐ Renewal Application

1.0 COVER LETTER

Addressed to:

THE CHIEF EXECUTIVE OFFICER
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS, ACCRA
GHANA.

***NB**: Where the manufacturing site is more than one, a separate application is required in respect of each premises except where a group of buildings on one or more sites are engaged in making the same kind of product under the same direct production and quality control management*.
For extra information refer to Guidelines for Licensing of Premises for the Manufacture of Medical Devices - FDA/MCH/MID/GL-MD- GMP 2019/01.

2.0 GENERAL INFORMATION OF THE COMPANY/FACILITY

(a) Name of Manufacturer: ……

(b) Corporate Address of Manufacturer:

Postal Address: ……..

Tel No: ……

Email: ……..

Website: ……..

Fax: ……..

(c) Factory Location Address:

Street Address: ……..……

Nearest Landmark: ……..

Digital Address:……..……

Tel No: ……...

Email: ……

Website: (if different from above)..……

Fax: (if different from above)……..

NB: Street Address refers to House No., Street Name & Town/City

(d) Additional Manufacturing* site (if any)

Street Address: ……..……

Nearest Landmark: ……..……..

Digital Address:……..……

Tel No: ……...

Email: …….

Website: (if different from above)..…….

Fax: (if different from above)…..……..

NB: Street Address refers to House No., Street Name & Town/City

* Manufacturing is defined as production of products or engaging in any part of the process of producing the product or bringing the products to their final stage. This includes processing, assembling, packaging, labeling, storage, sterilizing, testing or release for supply of the products or of any component or ingredient.

(e) Contact Person Name: ……..……..

Tel No: ……

Email: ……

3.0 CATEGORY OF PRODUCTS

(a) Indicate the class of medical devices manufactured or to be manufactured *(Tick the appropriate box (es))*

- ☐ Diapers and Sanitary Pads
- ☐ Class I Devices
- ☐ Class II-IV Devices

(b) State other products manufactured or to be manufactured at the same premises which do not fall within the categories listed in **3.0 (a)**, if any.

- ……
- ……
- ……

(c) Indicate the device's medical specialty (Global Medical Device Nomenclature – GMDN).
(Tick the appropriate box (es)

- ☐ Sanitary Devices
- ☐ Anesthesiology
- ☐ Cardiovascular
- ☐ Chemistry
- ☐ Dental Part
- ☐ Ear, Nose, and Throat
- ☐ Gastroenterology and Urology
- ☐ General and Plastic Surgery
- ☐ General Hospital
- ☐ Hematology
- ☐ Immunology
- ☐ Microbiology
- ☐ Neurology
- ☐ Obstetrical and Gynecological
- ☐ Ophthalmic
- ☐ Orthopedic
- ☐ Pathology
- ☐ Physical Medicine
- ☐ Radiology
- ☐ Toxicology
- ☐ Any Other (please specify…….

4.0 KEY PERSONS (PRODUCTION/QUALITY CONTROL/QUALITY ASSURANCE)

(a) Person in charge of production

Full Name……

Position in the company……

Relevant Qualifications		
Name of Institution	Duration of Study	Certificates Awarded
Relevant Experience		
Name of Company	Duration	Position Held

(b) Person(s) in charge of Quality Control/Quality Assurance

Full Name……

Position in the company……

Relevant Qualifications		
Name of Institution	Duration of Study	Certificates Awarded
Relevant Experience		
Name of Company	Duration	Position Held

5.0 NUMBER AND CATEGORY OF EMPLOYEES

(a) Estimated number of employees required:

Category	Initial Capacity	Full Capacity
Managerial		
Senior Skilled		
Junior Skilled		
Unskilled		

(b) Would any expatriate be employed? ☐ Yes ☐ No

If Yes,

(i). How many? ……..

(ii). What are their nationalities? .....

……

……..

……..

6.0 SPECIFICATION OF THE PLANT

(a) Scale of manufacturing

☐ Micro ☐ Small ☐ Medium ☐ Large

(b) Type of Equipment

Name or Type of Equipment	Number of Units	Capacity

(Attach supplementary list where necessary)

(c) What is the projected maximum annual capacity of the proposed plant?

……..

(d) Indicate number of shifts…….

(e) What are your anticipated sources of raw materials?

……

……

……

NB: You may attach a table indicating a list if raw materials and their corresponding suppliers.

7.0 WATER SUPPLY, TREATMENT AND WASTE DISPOSAL

(a) What is your source of water supply?.....

(b) Proposed water treatment method……

(c) Proposed effluent treatment methods before discharge……..

8.0 CONTRACT MANUFACTURE (WHERE APPLICABLE)

Is the company engaged in contract manufacturing?

☐ Yes ☐ No

If Yes, complete the following and attach a copy of the Contract Agreement (but if No, state "Not Applicable")

(a) Product stages of manufacture (excluding testing) which are to be contracted to another manufacturer.

Product/ Stage	Manufacturer	Address

(b) Testing contracted to another manufacturer

Nature of Test	Name of Testing Laboratory/Service	Address

(c) Products stages of manufacture, including testing, which are to be made or performed for another manufacturer.

Product/Stage	Manufacturer	Address

9.0 ADDITIONAL INFORMATION

(a) State proposed date of commencement of business…….

(b) Any additional information which applicant wishes to provide…….

……

10.0 DECLARATION

I/We hereby confirm that the information provided in this application form are true and correct to the best of my/our knowledge.

Name of Owner/Director ……

Signature……..

Date……..

Stamp……..……

Name of Qualified/Person ……

Qualification…….

Signature……..

Date……..……..

Stamp…….……

*** Witnessed by/Name** ……..

Signature……

Date……...

Stamp……...

(* Senior Civil/ Public Servant, Minister of Religion)

11.0 ATTACHMENTS

The following are to be attached (tick if submitted):

- ☐ Copy of Certificate of Incorporation and Certificate of Commencement of Business from Registrar General's Department
- ☐ Certified Copy of Power of Attorney (where applicable, to be attached)
- ☐ Site Master File
- ☐ Environmental Protection Agency (EPA) Permit (where necessary)
- ☐ List of Equipment and their capacity
- ☐ Name and address of suppliers of equipment.
- ☐ Technical management agreement signed with any organization
- ☐ Building plan (Floor plan)
- ☐ Contract Agreement (Where necessary)